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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/121,798	07/23/98	BRIDENBAUGH	R 018484-00129.1
			EXAMINER

HM22/0317

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KLINZ, G ART UNIT	PAPER NUMBER
	5

1623

DATE MAILED: 03/17/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 7-23-98 AND 10-5-98
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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PTOL-326 (Rev. 9/96)

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35 USC 103 Rejection

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 - 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wan et al. (5,837,529) in view of Ogawa et al. (EP 431905A1).

The claims are directed to a method for purifying plasmid DNA comprising (a) contacting the cells with a lysis solution, (b) flowing the lysis mixture through a first static mixer, c) contacting the lysed cell solution with a precipitation solution, (d) flowing the lysed cell solution and the precipitation solution through a second static mixer, (e) centrifuging the precipitation mixture thereby forming a precipitate and a clarified solution, (f) neutralizing either the precipitate or the clarified solution, and (g) contacting the clarified solution with an anion exchange chroma-

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tography resin and eluting the plasmid DNA with a saline step or continuous gradient. Claim 2 specifies that the method also comprise an RNase digestion. Claim 3 specifies that the lysis solution contain alkali. Claim 4 specifies that the precipitation solution contain potassium acetate. Claim 5 requires that the neutralizing step (f) precede the centrifugation step (e). Claim 6 and 9 requires specifies that the velocity of the first static mixer (0.38 to 2.3 ft per sec) and the diameter of the second static mixer (3/16 to 2 inches). Claims 7 and 11 specifies that the first and second static mixers have 24 elements. Claims 8 and 10 requires that the static mixer be a laminar flow static mixer. Claims 12 - 16 requires two or more of the steps of the method be performed simultaneously. Claims 17 requires that the method be automated.

Wan et al. discloses applicant's process steps (a) - (d) that require two static mixers in claims 11-16. The lysis buffer can include alkali and enzymes, such as RNase (column 3, lines 16-22). The precipitating agents include potassium acetate (column 3, lines 49-50). Wan et al. does not disclose centrifuging the pellet the precipitate as in step (e). However, Wan et al. does disclose the formation of a precipitate by potassium acetate (column 4, lines 20-28). The removal of a precipitate by centrifugation is a routine technique in DNA purification. Wan et al. also does not disclose neutralization of the clarified supernatant followed by anion exchange chromatography.

However, Ogawa et al. does disclose a method for purifying DNA comprising anion exchange chromatography and ultrafiltration. The neutralization of a highly basic solution prior to contacting said solution to an anion exchange column would have been routine, otherwise, the

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plasmid would have been unlikely to bind to the resin. Therefore, it would have been obvious to the person of ordinary skill in the art at the time of the invention to have combined the plasmid purifying process of Wan et al. with the additional anion exchange chromatography and/or ultrafiltration steps taught by Ogawa et al. for the purpose of obtaining a purified plasmid preparation that would be of pharmaceutical grade purity. Thus, the claimed invention is prima facie obvious in the absence of clear and convincing evidence to the contrary. The applicant has not established the criticality of any of the limitations in the dependent claims. The combining of two or more steps in the process would have been also obvious for the purpose of simplifying the process and reducing the time of cost of purification.

Claims 17 - 19 were not included in the above obviousness rejection because they include the use of an ultrafiltration step in the presence of a gel. This limitation was reason that the parent case was allowed over Ogawa et al.

Obviousness Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 - 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 62 of copending Application No. 08/691,090 in view of Wan et al. (5,837,529). The only substantial differences between the claimed invention and that disclosed by the allowed parent case is the use of static mixers in the plasmid isolation prior to the use of ultrafiltration and/or anion exchange chromatography. However, as explained above, Wan et al. discloses steps (a)-(d) that require two static mixing steps. Therefore, it would have been obvious to have modified the process as claimed in the parent applicant by adding the plasmid isolation steps taught by Wan et al. for the purpose obtaining a plasmid isolation procedure that can be readily automated.

This is a provisional obviousness-type double patenting rejection.

Rejection under 35 USC 112, Second Paragraph

Claims 1 - 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite because neutralizing the pellet in step (f) makes no sense when the plasmid is contained in the clarified supernatant.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marion Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200